



Lilly's oral GLP-1, Foundayo (orforglipron), demonstrated cardiovascular safety alongside sustained A1C reduction and weight loss in its largest and longest type 2 diabetes study

September 30, 2026

In ACHIEVE-4, participants taking Foundayo experienced a 16% lower risk of MACE-4 and a 23% lower risk of MACE-3, meeting the primary objective for non-inferiority compared to insulin glargine

In pre-planned analyses, Foundayo showed a 53% lower risk of cardiovascular death and a 57% lower risk of all-cause death vs. insulin glargine, suggesting the potential for more comprehensive health benefits

INDIANAPOLIS, Sept. 30, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY), the maker of Zepbound (tirzepatide), today announced detailed results from the Phase 3 ACHIEVE-4 trial evaluating the efficacy and safety of Foundayo (orforglipron) compared to titrated insulin glargine in adults with type 2 diabetes and obesity or overweight at increased cardiovascular risk. In the trial, which is the largest and longest study of this medicine in type 2 diabetes to date, Foundayo demonstrated a non-inferior risk of major adverse cardiovascular events (MACE) and improved A1C, weight and other key measures of cardiometabolic health compared with insulin glargine. Results from the trial were presented at the 62nd Annual Meeting of the European Association for the Study of Diabetes (EASD) in Milan, Italy, and simultaneously published in *The Lancet*.

"For people living with type 2 diabetes, protecting the heart is as important as controlling blood sugar," said Klara Klein, M.D., Ph.D., Assistant Professor of Medicine, University of North Carolina School of Medicine. "ACHIEVE-4 reaffirmed the safety of orforglipron and demonstrated an association with a lower risk of major cardiovascular events and death. These results, paired with the simple administration of a once-daily pill, taken without fasting or water restrictions, could make orforglipron a compelling potential option across the globe."

In the trial, the risk of cardiovascular death, heart attack, stroke, or hospitalization for unstable sudden chest pain (MACE-4) was 16% lower for Foundayo vs. insulin glargine (hazard ratio: 0.84; 95.0% CI: 0.59 to 1.20), meeting the prespecified criteria for demonstrating non-inferiority (upper limit of 95.0% CI of the hazard ratio < 1.8).¹ The risk of cardiovascular death, heart attack, or stroke (MACE-3) was 23% lower for Foundayo vs. insulin glargine (hazard ratio: 0.77; 95.0% CI: 0.52 to 1.13). In pre-planned analyses, the risk of cardiovascular death was 53% lower (hazard ratio: 0.47; 95.0% CI: 0.25 to 0.90) and the risk of all-cause death was 57% lower (hazard ratio: 0.43; 95.0% CI: 0.25 to 0.75) for Foundayo vs. insulin glargine.²

In addition to demonstrating cardiovascular safety, Foundayo was associated with meaningful improvements across multiple cardiovascular risk factors. At week 52, participants treated with Foundayo experienced reductions in waist circumference by 7.0 cm, systolic blood pressure by 4.4 mmHg, triglycerides by 18.9%, non-HDL cholesterol by 6.6% and hsCRP, a marker of inflammation, by 38.9%.² Foundayo was also associated with a slower decline in kidney function, a key contributor to cardiovascular risk, including a 2.8 mL/min/1.73 m² smaller reduction in eGFR and a 27.1% greater reduction in albuminuria compared to insulin glargine.²

ACHIEVE-4 Detailed Results

	Foundayo	Insulin Glargine
Primary Endpoint		
Time to first occurrence of MACE-4 ⁱ	Hazard ratio = 0.84 95.0% CI: 0.59 to 1.20 ⁱⁱ p = 0.336	
Key Secondary Endpoints		
Time to first occurrence of MACE-3 ⁱ	Hazard ratio = 0.77 95.0% CI: 0.52 to 1.13 p = 0.181	
Change in A1C from mean baseline of 8.22% at 52 Weeks ⁱⁱⁱ	-1.6 %	-1.0 %
	Estimated treatment difference: -0.66 (95.0% CI: -0.74 to -0.58) p <0.001	
Change in body weight from mean baseline of 90.9 kg (200.4 lbs; BMI of 32.6 kg/m²) at 52 Weeks ⁱⁱⁱ	-8.8% (-8.1 kg / -17.9 lbs)	+1.7% (+1.4 kg / +3.1 lbs)
	Estimated treatment difference: -10.42% (95.0% CI: -10.92 to -9.93) p < 0.001	
Secondary Endpoints at 104 Weeks		
Percent of participants achieving A1C ≤6.5% ^{iii, iv}	54.6 %	23.8 %
Percent of participants achieving body weight reduction of ≥10% ^{iii, iv}	35.9 %	3.4 %
Additional Pre-Planned Analysis		

All-cause death ^{i,iv}	Hazard ratio = 0.43 95.0% CI: 0.25 to 0.75 p = 0.002
Cardiovascular death ^{i,iv}	Hazard ratio = 0.47 95.0% CI: 0.25 to 0.90 p = 0.019

ⁱTime to first event analysis using Cox proportional hazard model for CI and log-rank for p-value. All data from randomization to end of the study were included in the analysis.

ⁱⁱNon-inferiority (upper limit of 95% CI of the hazard ratio < 1.8).

ⁱⁱⁱResults of A1C and body weight were based on efficacy estimand.³

^{iv}Not controlled for family-wise type 1 error.

"Foundayo has consistently delivered strong efficacy in type 2 diabetes across our Phase 3 ACHIEVE program," said Thomas Seck, M.D., senior vice president of product development, Lilly Cardiometabolic Health. "In ACHIEVE-4, our largest and longest study of this medicine, Foundayo helped more than half of participants reach an A1C of 6.5% or lower, with durable reductions in A1C and body weight and a favorable overall safety profile. This kind of efficacy reinforces our confidence that Foundayo could change how physicians and patients approach the treatment of type 2 diabetes."

The overall safety and tolerability profile of Foundayo in ACHIEVE-4 was generally consistent with previous trials and with other incretins. The most common adverse events for participants taking Foundayo were nausea, vomiting, diarrhea, decreased appetite, and constipation. During the 52-week minimum treatment period, 10.6% of participants taking Foundayo discontinued treatment due to adverse events.

To further evaluate the impact Foundayo has on cardiovascular outcomes in adults with obesity or overweight with or without type 2 diabetes, Lilly is conducting ATTAIN-OUTCOMES, an ongoing Phase 3 study in adults with established cardiovascular or kidney disease.

About Foundayo (orforglipron)

Foundayo™ (orforglipron) is FDA-approved for adults with obesity, or some adults with overweight who also have weight-related medical problems, to reduce excess body weight and maintain weight reduction long term, alongside a reduced-calorie diet and increased physical activity. Foundayo is a once-daily small molecule (non-peptide) oral glucagon-like peptide-1 receptor agonist that can be taken any time of the day with no planning around food or drink.

Orforglipron was discovered by Chugai Pharmaceutical Co., Ltd. and licensed by Lilly in 2018. In addition to chronic weight management, orforglipron is being studied as a potential treatment for type 2 diabetes, obstructive sleep apnea, osteoarthritis knee pain, hypertension, peripheral artery disease and stress urinary incontinence.

About ACHIEVE-4 and ACHIEVE clinical trial program

ACHIEVE-4 (NCT05803421) is a Phase 3, event-driven, randomized, open-label trial evaluating the efficacy and safety of Foundayo compared with insulin glargine U-100 in adults with type 2 diabetes and obesity or overweight (BMI ≥25 kg/m²) with increased risk of cardiovascular events. The trial randomized 2,749 participants across the U.S., Argentina, Austria, Brazil, Czechia, Germany, Greece, India, Italy, Mexico, Puerto Rico, Romania, Slovakia, South Korea, Spain and Turkey to receive either escalating doses of Foundayo or insulin glargine. The primary objective of the study was to demonstrate that Foundayo was non-inferior in the risk of major adverse cardiovascular events (MACE-4) compared to insulin glargine in adults with type 2 diabetes and obesity or overweight with increased risk for cardiovascular events who have taken at least one and no more than three oral anti-diabetic medications for at least 90 days prior to study start. Study participants had an A1C between ≥7.0% and ≤10.5% (≥7.5% and ≤10.5% if background diabetes medication included a sulfonylurea) and a BMI of ≥25 kg/m² with stable weight (±5%) for at least 90 days prior to study start. Participants randomized to Foundayo initiated treatment with 0.8 mg once daily and increased the dose every four weeks until reaching a maximum tolerated dose (up to 17.2 mg). The trial was conducted using an investigational formulation of Foundayo at dosages equivalent to Foundayo tablets.

The ACHIEVE Phase 3 global clinical development program for Foundayo began in 2023 and enrolled more than 6,000 people with type 2 diabetes across five global registration trials.

Endnotes

1. Time to first event analysis using Cox proportional hazard model using all randomized participants exposed to ≥1 dose of study intervention.
2. All-cause death, waist circumference, serum lipids, blood pressure, hsCRP, cardiovascular death and kidney function endpoints were not controlled for family-wise type 1 error. Waist circumference, eGFR, albuminuria, serum lipids, blood pressure and hsCRP were based on efficacy estimand.
3. The efficacy estimand represents efficacy had all randomized participants remained on study intervention (with possible dose interruptions and/or dose modifications) without initiating additional antihyperglycemic medications (>14 days of use).

U.S. FOUNDAYO INDICATION AND SAFETY SUMMARY WITH WARNINGS

Foundayo (fown-DAY-oh) is a prescription medicine used with a reduced-calorie diet and increased physical activity to help adults with obesity, or some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.

- Foundayo should not be used with other GLP-1 receptor agonist medicines.
- It is not known if Foundayo is safe and effective for use in children.

Warnings – Foundayo may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Foundayo if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Foundayo if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Foundayo if you have had a serious allergic reaction to orforglipron or any of the ingredients in Foundayo.

Foundayo may cause serious side effects, including:

Inflammation of the pancreas (pancreatitis). Stop taking Foundayo and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without nausea or vomiting. Sometimes you may feel the pain from your abdomen to your back.

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Foundayo. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Foundayo with medicines that can cause low blood sugar, such as an insulin or sulfonylurea. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood changes, hunger, weakness, or feeling jittery.

Serious allergic reactions. Stop using Foundayo and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, or very rapid heartbeat.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Foundayo.

Gallbladder problems. Gallbladder problems have happened in some people who use Foundayo. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), or clay-colored stools.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Foundayo may increase the chance of food getting into your lungs during surgery or other procedures. Tell your healthcare providers that you are taking Foundayo before you are scheduled to have surgery or other procedures.

Common side effects

The most common side effects of Foundayo include nausea, constipation, diarrhea, vomiting, indigestion, stomach (abdominal) pain, headache, swollen belly, feeling tired, belching, heartburn, gas, and hair loss. These are not all the possible side effects of Foundayo. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your doctor if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before taking Foundayo

- **Tell your healthcare provider about all the medicines you take.** Foundayo may affect the way some medicines work, and some medicines may affect the way Foundayo works.
- **Pregnancy Exposure Registry:** There will be a pregnancy exposure registry for women who have taken Foundayo during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).
- **If you take birth control pills by mouth, talk to your healthcare provider before you take Foundayo. Birth control pills may not work as well while taking Foundayo.** Your healthcare provider may recommend another type of birth control for 30 days after starting Foundayo and for 30 days after each dose increase of Foundayo.
- **Talk to your healthcare provider about low blood sugar and how to manage it.** Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea.

Review these questions with your healthcare provider:

- ☐ Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your liver, severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ☐ Do you have a history of diabetic retinopathy?
- ☐ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
- ☐ Are you pregnant or plan to become pregnant? Foundayo may harm your unborn baby.
- ☐ Are you breastfeeding or plan to breastfeed? Breastfeeding is not recommended during treatment with Foundayo.
- ☐ Do you take any other prescriptions or over-the-counter medicines, vitamins, or herbal supplements?

How to take

- Take Foundayo exactly as your healthcare provider tells you to.
- Use Foundayo with a reduced-calorie diet and increased physical activity.
- Take Foundayo by mouth 1 time each day, with or without food.

- Swallow tablets whole. Do not break, crush, or chew the tablet.
- If you miss a dose, take it as soon as possible. **Do not** take 2 doses of Foundayo in the same day.
- **Do not take more than 1 tablet per day.**
- If you miss taking Foundayo for 7 or more days in a row, call your healthcare provider to talk about how to restart your treatment.
- If you take too much Foundayo, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more

Foundayo is a prescription medicine available in 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, or 17.2 mg oral tablets. For more information, call 1-800-545-5979 or go to foundayo.lilly.com.

This summary provides basic information about Foundayo but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Foundayo and how to take it. Your doctor is the best person to help you decide if Foundayo is right for you.

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U.S. ZEPBOUND INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Zepbound® (ZEHP-bownd) is an injectable prescription medicine used with a reduced-calorie diet and increased physical activity to help adults with:

- obesity, or some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.
- moderate-to-severe obstructive sleep apnea (OSA) and obesity to improve their OSA.

Zepbound contains tirzepatide and should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines. It is not known if Zepbound is safe and effective for use in children.

Warnings - Zepbound may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Zepbound if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Zepbound if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Zepbound if you have had a serious allergic reaction to tirzepatide or any of the ingredients in Zepbound.

KwikPen®: Do not share your KwikPen with other people, even if the pen needle has been changed. You may give other people a serious infection or get a serious infection from them.

Zepbound may cause serious side effects, including:

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Zepbound. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Gallbladder problems. Gallbladder problems have happened in some people who use Zepbound. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), or clay-colored stools.

Inflammation of the pancreas (pancreatitis). Stop using Zepbound and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without nausea or vomiting. You may feel the pain from your abdomen to your back.

Serious allergic reactions. Stop using Zepbound and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, or very rapid heartbeat.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Zepbound with medicines that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar** may include dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood changes, hunger, weakness or feeling jittery.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Zepbound.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Zepbound may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Zepbound before you are scheduled to have surgery or other procedures.

Common side effects

The most common side effects of Zepbound include nausea, diarrhea, vomiting, constipation, stomach (abdominal) pain, indigestion, injection site reactions, feeling tired, allergic reactions, belching, hair loss, and heartburn. These are not all the possible side effects of Zepbound. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your doctor if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before using Zepbound

- **Your healthcare provider should show you how to use Zepbound before you use it for the first time.**
- **Talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Zepbound. Birth control pills may not work as well while using Zepbound.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Zepbound and for 4 weeks after each increase in your dose of Zepbound.

Review these questions with your healthcare provider:

- ☐ Do you have other medical conditions, including problems with your pancreas, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ☐ Do you take diabetes medicines, such as insulin or sulfonylureas?
- ☐ Do you have a history of diabetic retinopathy?
- ☐ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
- ☐ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?
- ☐ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? Zepbound may harm your unborn baby. Tell your healthcare provider if you become pregnant while using Zepbound. Zepbound may pass into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using Zepbound.

- **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for women who have taken Zepbound during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may call 1-844-524-0039 or email at MILEregistry@thermofisher.com or visit <https://pregnancyregistry.lilly.com/zepbound>.

How to take

- Read the Instructions for Use that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- Use Zepbound with a reduced-calorie diet and increased physical activity.
- Inject Zepbound under the skin (subcutaneously) of your stomach (abdomen), thigh, or have another person inject in the back of the upper arm. **Do not** inject ZEPBOUND into a muscle (intramuscularly) or vein (intravenously).
- **Use Zepbound 1 time each week, at any time of the day.**
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.

If you take too much Zepbound, call your healthcare provider, call the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Zepbound is approved as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg injection.

Learn more

Zepbound is a prescription medicine. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.zepbound.lilly.com.

This summary provides basic information about Zepbound but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Zepbound and how to take it. Your healthcare provider is the best person to help you decide if Zepbound is right for you.

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About Lilly

Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative

clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit [Lilly.com](https://lilly.com) and [Lilly.com/news](https://lilly.com/news), or follow us on [Facebook](https://www.facebook.com/lilly), [Instagram](https://www.instagram.com/lilly), and [LinkedIn](https://www.linkedin.com/company/lilly). P-LLY

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Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Foundayo (orforglipron) as a potential treatment for adults with type 2 diabetes, potential efficacy and tolerability of Foundayo, and the timeline for future readouts, presentations, and other milestones relating to Foundayo and its clinical trials and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with expectations or study results to date, that Foundayo will prove to be a safe and effective treatment for type 2 diabetes, that Foundayo will receive additional regulatory approvals, or that Lilly will execute its strategy as expected. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Refer to: Niki Biro; niki_biro@lilly.com (Media)

Michael Czapar; czapar_michael_c@lilly.com (Investors)

The Lilly logo is rendered in a vibrant red, flowing script font. The letters are interconnected, with a large, elegant 'L' at the beginning and a long, sweeping tail on the 'y' that extends downwards and to the right.

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